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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/345,824	06/30/99	LETAC	B 66066

022242 QM22/0829
FITCH EVEN TABIN AND FLANNERY
120 SOUTH LA SALLE STREET
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CHICAGO IL 60603-3406

EXAMINER

PELLEGRINO, B

ART UNIT	PAPER NUMBER
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3738

8

DATE MAILED: 08/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/345,824

Applicant(s)

Letac et al.

Examiner

Brian Pellegrino

Group Art Unit

3738

☒ Responsive to communication(s) filed on Jun 1, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-32 is/are pending in the application.

Of the above, claim(s) 28-32 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-27 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 27-32 are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☒ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

An error occurred in the previous restriction with claim 27 being improperly restricted in Group I with claims 1-26. Claim 27 recites a balloon catheter, therefore should be included in Group II (claims 28-30) of the restriction

Claim Objections

1. Claims 12-14 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Claim 12 depends from multiple dependent claims 4 and 5.

Claim 27 is objected to as not being in proper U.S. form for referring to a claim multiple times..

Claim Rejections - 35 U.S.C. § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Regarding claim 4, it is not understood how the "valvular structure and cover" can be one-piece because claim 2 recites the elements as being coupled.

With respect to claim 5, the claim is indefinite because the use of the phrase "and/or" renders the claim indefinite.

Claim 11 recites the limitation "the strips" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Regarding claims 15 and 24, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Additionally, it is unclear what is meant by the "main parts" in claim 15.

Claim 17 recites the limitation "other parts" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

With respect to claim 18, it is unclear what is meant by "completed" in line 2.

Regarding claim 19, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 25 recites the limitation "the bars" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim. Did applicant intend to have dependency to claim 24 instead of 23?

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Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 6, 8, 10, 12, 14, 15, 17 as best understood, 18-20, 23, 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Boretos et al. (4265694). Figures 1 and 2 teach that a frame 12 can be used to form a valve prosthesis having valvular structures (14a, 14b, 14c) mounted on said frame (Fig. 2). It can be construed that the "radiating lines" 22 are "guiding means" that form stiffened zones, col. 7, lines 1-7. Regarding claim 4, see col. 7, lines 41-43 teaching to make the valvular structure as one-piece. Regarding claims 8 and 10, see Fig. 1 showing at least three struts being concave towards the upper extremity. With respect to claim 14, see col. 7, lines 45-46. It can also be construed that stiffened zones 22 are "main parts" and membrane 14 is another part of less rigid material and thinner.

5. Claims 1, 15 as best understood, 16, 19, 20, 23, 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Dzemeshevich et al. (4692164). Figure 3 shows an expandable frame 4 with struts 9 attached thereto that can be construed as "guiding means." A covering 5 is mounted to the external frame. Figure 11 shows a heart valve in which the main parts 25, 23 can be construed as being of trapezoidal shape. Additionally, each of the main parts of the prosthetic valve 1, occupies "approximately" one third of the circumference of the upper part of the

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valvular structure. Regarding claim 19, see col. 3, lines 59-62 teaching that natural donor material can be used. With respect to claim 20, see col. 14, lines 53-62. Regarding claim 23, see col. 11, line 19. Figure 4 teaches that the frame is made of "intercrossing" bars.

6. Claims 1, 21, 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Andersen et al. (5411552). Andersen et al. teach to form a valve prosthesis from a collapsible stent of metal wires which has a valve mounted thereon, col. 5, lines 9-14. With respect to claim 21, see col. 8, lines 49-50 teaching a diameter for the expanded frame that falls within the claimed range. Regarding claim 22, see col. 8, lines 44-46 teaching a height that falls within the claimed range.

7. Claims 1-5, 7, 11, 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevens (5545214). Figure 11 teaches a valve prosthesis having a frame 85 upon which a valvular structure 80 is mounted, col. 8, lines 16-22. Regarding claim 2 and the inclusion of an internal cover, col. 8, lines 30-32 teaches that additional layers can be attached to the device. With respect to claim 5, col. 8, lines 34-36 teach the valvular structure is made of anti-thrombic materials. Regarding claim 11, see col. 8, lines 22-26. Regarding claims 23-25, see col. 8, lines 60-67 teaching the material to make the frame and Fig. 11 showing the intercrossing bars.

Claim Rejections - 35 U.S.C. § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 2, 5, 6, 21-23, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler et al. (5855601) in view of Boretos et al. (4265694). Figure 4 of Bessler et al. teaches that a heart valve can be constructed with a stent 32 of a material detectable by noninvasive imaging techniques, col. 6, lines 3-7. They teach to couple the valvular structure within the internal wall of the stent frame, (col. 3, lines 57-60). Additionally, Bessler et al. teach to form the valvular structure of an anti-thrombic material, col. 6, lines 19-29. Regarding dimensions of the stent frame, see col. 6, lines 14-18. It can also be seen that the stent frame has projecting curved bars 34 at the extremities. However, what Bessler et al. fail to teach is to include "guiding means" with stiffened zones. Boretos et al. teach to include reinforcement lines in the leaflets to increase the stability of the valve. It would have been obvious to one of ordinary skill in the art to modify the leaflets of Bessler et al. and include the reinforcement lines as taught by Boretos et al. As a result these "built-in struts" or lines aid in preventing prolapse of the leaflets, col. 7, lines 1-7 of Boretos et al.

10. Claims 9, 13, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boretos et al. in view of Trescony et al. (5282847). Boretos is explained as before. However, what they fail to teach is to provide the valvular structure with pleats. Trescony et al. teach that a graft can be constructed with pleats (Fig. 1) extending from the base to the top of the structure in order to accommodate blood pressure changes in the vessel to which it is implanted. The pleats can be

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interpreted as being continuous rectangular shapes joined as folds. It would have been obvious to one of ordinary skill in the art to modify the valvular structure (Fig. 2) of Boretos et al. and incorporate pleats in the leaflets as taught by Trescony et al. to aid in kink resistance.

Additionally, hyperplasia will be reduced, col. 4, lines 17-22 of Trescony.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kusuhara (5360444) teaches to cover surfaces of a support for a heart valve with antithrombotic material or coatings.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8am to 5:30pm. The examiner can also be reached on alternate Fridays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vincent Millin, can be reached on (703) 308-1065. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Brian E. Pellegrino

August 21, 2000


Michael J. Milano
Primary Examiner
TC 3700, AU 3738